Promotion of Successful Weight Management in Overweight and Obese Veterans

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January 19, 2021

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: __Promotion of Successful Weight Management in Overweight and Obese Veterans __

Facility: VA Maryland Health Care System

IRB Study Number: HP-00088304
Sponsor: The U.S. Department of Veterans Affairs, Office of Research & Development (ORD)

INTRODUCTION: You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS), University of Maryland, Baltimore (UMB) and South Texas VA Medical Center. If you are signing this form, your study participation would occur almost entirely at VAMHCS, with the possibility of only one testing procedure being done at UMB. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

CONCISE SUMMARY

Important Information
This section gives you an overview of the research that you are being asked to participate in. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future**.**
The research in this study will compare the effects of a weight maintenance diet and exercise plan with and without intermittent fasting to prevent weight regain following successful weight loss in overweight and obese Veterans. Intermittent fasting involves periods of decreased food intake (typically <700 calories per day) for a few days of the month. Intermittent fasting could have an impact on preventing body weight regain common after successful weight loss.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?

You will be one of 120 individuals who will participate in this research study occurring locally at the VAMHCS and UMB. We plan to enroll a total of 220 overweight and obese Veterans into a 12-week weight loss program that incorporates a low calorie, heart healthy diet and exercise. Following the 12-week weight loss program, Veterans will be randomized (like a flip of a coin) to either a 24-week weight maintenance program (continuation of a heart healthy diet and exercise guidelines) or the same 24-week weight maintenance program combined with periodic intermittent fasting. We would like to examine the effects of the 12-week weight loss and 24-week weight maintenance programs on your body composition (fat and muscle quantities), physical activity habits, stress, hormone and protein production, and physical performance (such as walking and balance). We would also like to assess whether changes in these physical characteristics during weight loss and weight maintenance are controlled by changes in markers in the blood and skeletal muscle. We will take a small sample of your thigh muscle using a special needle after you have fasted for 10-12 hours.

3. How much time will I spend on the study?

It is important to keep in mind that this study involves a large amount of time and effort. If you agree to participate, we will request that you make multiple (~35) visits to our local Baltimore facilities (VAMHCS and possibly UMB) over approximately 11-12 months. You will complete research testing prior to starting the initial 12-week weight loss part of the study. You also will complete tests after 12 weeks of weight loss, and after 24 weeks of weight maintenance. The weight loss part of the study will require you to come to the VA to exercise and learn about healthy eating and weight loss behaviors 2 times per week for 12 weeks and the weight maintenance part of the study will require that you speak to a study team member 2-4 times per month by phone.

4. Could taking part in the study help me and are there risks?

You may or may not benefit by taking part in this study. The benefits of participating in this study may be that your body composition, general health, and daily function may improve. The most common risks of this study include the possibility of muscle and joint discomfort from exercise, and tenderness from the collection of muscle tissue.

If still interested after reading the above summary, please review the rest of this document for additional details before making a final decision about study participation.

Participant Name: _____ Date:_____

Title of Study: __Promotion of Successful Weight Management in Overweight and Obese Veterans __

Facility: VA Maryland Health Care System

RESEARCH DETAILS

PURPOSE OF THE STUDY

Though weight loss of as little as 3% of body weight improves physical functioning and reduces type 2 diabetes and cardiovascular risk factors, most people are unsuccessful at long-term weight loss maintenance (i.e. staying at the lower weight for an extended period of time). In most cases, people regain almost half the weight lost within the next two years. You are asked to participate in this research study which aims to compare the effects of a weight maintenance diet and exercise plan with and without intermittent fasting to prevent weight regain following successful weight loss in overweight and obese Veterans. Intermittent fasting involves periods of decreased food intake (typically <700 calories per day) for a few days of the month. Intermittent fasting could have an impact on preventing body weight regain common after successful weight loss.

The researchers hope to learn about ways to support long term weight maintenance in overweight and obese Veterans that have recently gone through successful weight loss.

This trial may be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You are being asked to be a participant in this study because you are a Veteran between the ages of 50-75 years and are overweight or obese. You will be one of approximately 120 individuals who participate in this research study locally at VAMHCS/ UMB (approximately 220 will participate nationally).

This is a "collaborative" study that will combine VAMHCS/ UMB research activities and data with South Texas VA Medical Center research activities and data. The study is coordinated from the VAMHCS location.

STUDY PROCEDURES:

While you are taking part in this study, you will be asked to attend approximately 35 visits with the researchers or study staff over an 11-12-month period. This study will occur over 6 phases described below. All these study procedures are done solely for research. Most take place at the Baltimore VA Medical Center (BVAMC, BVAMC Annex, and/or BVAMC Loch Raven Outpatient Clinic) One study procedure (muscle sampling, see below) may take place at University of Maryland Medical Center General Clinical Research Center (UMMC-GCRC, 10th Floor, D wing) or at the BVAMC.

Phase 1: Consent and Screening Procedures

This visit will take approximately 2-2.5 hours and will occur at the BVAMC in the Geriatric Research, Education and Clinical Center (GRECC- 4B wing of BVAMC). The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you qualify to continue in the study. If you do not qualify for the study based on screening results, the researcher will discuss the reasons with you.

Informed Consent: During the consent visit, we will review all details of the research program in private. You will be provided with adequate time to have your questions answered, concerns addressed or clarified, and for you to consider whether you wish to participate. You will be given a copy of the informed consent. You also will be asked to complete two tests. One will determine your ability to understand and think clearly. The other will test for depression. If you are eligible, you will be scheduled for the screening tests. If medical concerns can be addressed to correct the cause of ineligibility, you may contact us for re-screening.

Screening: After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study. This is called screening. These procedures are for research only.

A. Medical history & physical examination/assessment: An approved study or GRECC clinician will ask you questions regarding your medical history, and then will perform a physical exam, to determine whether you meet the requirements to continue in this study. The physical exam is like a routine physical exam performed by your primary care doctor. We may contact your medical doctor to request additional information about your medical history.

B. Blood draw: We will draw approximately 2 tablespoons from a vein in your arm for complete blood cell count, blood chemistry, cholesterol level, hemoglobin A1c (a diabetes test), thyroid, and blood clotting tests.

C. Electrocardiogram (ECG): We will place small, sticky patches on your chest that enable us to assess your heart function to check for any problems that might make it unsafe for you to participate in the regular exercise associated with this study.

Phase 2: Baseline Research Testing

These tests will occur over 4-5 visits and will take approximately 10 hours. All testing will occur at the BVAMC, except for the muscle sampling which may occur at UMMC-GCRC. You will be

asked to sign an additional consent form for the muscle sampling if you are scheduled to complete the test at UMMC-GCRC. You may be asked to repeat one or more of the research tests, if necessary, due to a technical error in its performance and/or measurement, if the sample obtained is not enough to study, or if there was an unexpected problem with data collection. The number of visits needed to complete testing and the order of these tests may vary based on the availability of staff, your availability, and your ability to complete tests without fatigue. The results of all tests will be available to you, except for the stored specimen results (described below). The results will be explained to you by the PI (lead investigator) and/or other study staff members.

A. Blood Sampling and Oral Glucose Tolerance Test (3 hours)

This test will be given after a 12 hour fast. We will collect about 3.5 tablespoons of blood after you have fasted for 10-12 hours to measure risk factors for diabetes and heart disease and markers associated with obesity. You also will undergo an oral glucose tolerance test. For this test, you will be asked to drink a glucose (sugar) solution, usually about 1 and ¼ cups. Blood (approximately one third of a tablespoon each time) will be drawn at 30 and 15 minutes before the sugar drink, at the time of the sugar drink, and then every 30 minutes for two hours afterwards to measure glucose, insulin (a natural hormone that regulates your glucose levels), and fatty acids. All blood will be drawn from a plastic intravenous catheter (a soft plastic narrow tube) that is inserted into a vein in your arm. The total amount of blood that will be drawn during the oral glucose tolerance test will be approximately 5.5 tablespoons.

Although we do not expect a problem with the collection of blood samples, should a problem arise, such as clotting or insufficient sample for analysis, we will draw up to an additional 3 tablespoons across your study participation.

B. Caloric Expenditure (about 30 min)

This test provides information about the rate at which your body burns calories. It requires that you are fasted (nothing to eat or drink) for 10-12 hours. You will lie quietly in bed for about 30 minutes while a large, clear plastic hood is fitted about the head. It has an opening to the air in the room. An opening at the front of the hood is attached to a rubber tube to collect and study the air you breathe out.

C. Walking and Balance (about 45 min)

You will have a series of tests to evaluate your walking and balance abilities. This includes:

- How far you can walk at a comfortable pace for 6 minutes.
- How long it takes you to stand up from a chair and sit down on a chair 5 times.

- How long it takes you to stand up from a chair and walk at various speeds at distances of about 10 meters and 50 feet.
- How long you can stand with your eyes open and closed, your feet together, one foot in front of the other foot.
- Your ability to remove a jacket, place a book on a high shelf, turn in a complete circle, climb a flight of stairs, and pick up a small object off the floor.

D. Cardiopulmonary Exercise Test (about 60 min)

You will complete a maximal exercise test on a treadmill as we measure your heart function, again using ECG and blood pressure recordings. A COVID-19 test may be performed, if indicated, at the first floor COVID testing suite at the BVAMC within 7 days prior to the treadmill test. This test involves a brief swab inside your nose for 15 seconds. If the test results do not show COVID-19, you will complete the treadmill test. If you have COVID-19, we will refer you to your primary care physician for care and not complete the treadmill test at that time. A study or GRECC clinician who is credentialed to conduct exercise tests will supervise this test. The exercise starts at low effort and gradually gets harder and harder (by elevating the treadmill grade/ incline) until you cannot continue walking any longer. We will also measure your breathing during the test, which means you must breathe through a facemask. This is so we can analyze the air you breathe out to measure your fitness level. Before starting the test, we will explain all of the testing equipment and what you have to do. If there are any problems during the test (for example, if you have chest pain or your legs tire), the test will be stopped immediately.

E. Muscle Strength Tests (about 60 minutes)

We will measure your muscle strength. For this test you will sit in a machine and push your legs or arms against resistance as hard as you can. This is done so we can measure the strength in specific muscles of your legs and upper body. You will perform these maximal strength measurements multiple times on 3 different machines. Your grip strength will also be measured using a hand-held device. You will be asked to hold your arm at 90 degrees and squeeze the handle of this device as hard as you can. You will do this three times with each hand.

H. Physical Activity Monitoring (about 10 min)

You will wear a monitor for 5-7 days to record how much activity you do during the day. The monitor is a small box (about the size of a beeper) that is worn on the waist or wrist.

I. Questionnaires (about 60 min)
You will complete questionnaires about your fatigue and pain levels, body weight history, activity levels, clarity of thinking, depression, mood, and quality of life.

J. Dietary Intake (about 30 min): A dietitian may ask you to recall everything that you have had to eat and drink during the previous 24 hours or a "typical" 24-hour period. The dietitian or study staff will provide instructions for you to record your daily food and drink intake during a 3-5-day period. This will be done to determine your current food and caloric patterns.

K. Muscle Sampling (about 1 hour): This test will be done at the BVAMC (4th floor GRECC) or the UMMC-GCRC (10th Floor, D wing). We will take a small sample of your thigh muscle using a special needle after you have fasted for 10-12 hours. These are called muscle biopsies. Occasionally a small amount of fat is also removed along with the muscle sample. If this occurs, we will save the fat sample to perform the same tests as in the muscle. To do this, we will clean your thigh and inject a local anesthetic (numbing medicine like your dentist uses) to numb a small area of your skin. We may have to shave a small area for the incision. We will clean the area with an iodine solution. Next, we will make a small cut in your skin (about ¼ inch). The biopsy needle will then be passed through this cut into the muscle and a piece of muscle tissue about the size of a pea will be obtained. At the time the muscle is obtained, many people feel pressure and a thumping sensation. About a third of people feel cramping or pain. The pain is mild to moderate and lasts 5-10 seconds. The pain stops when the needle is removed but your muscle may be sore for a few days. In the areas where the biopsies were done, we will apply strips of adhesive tape (steri strips) that will help the skin to close. The adhesive tape will come off on its own, and you do not need to peel it off. After the procedure, we will give you a meal and monitor how you feel. There is the possibility that a future biopsy may not be done at the discretion of the PI and medical staff in case you did not tolerate the first biopsy well or we did not get enough useful sample. The samples will be stored and analyzed at the BVAMC (3rd Floor Research Lab space in main hospital with access restricted to research lab staff).

L. Fecal Analysis: You will be asked to collect a small optional stool sample for assessment of how gut activity affects health and disease. Sample collection containers will be provided to you. On a day after the stool collection, the containers will be returned to the research center either in person or by mail. Samples will be analyzed at the University of Maryland School of Medicine, Institute for Genome Sciences.

M. Body Composition (about 1 hour): Tape measurements of several sites of your body will be determined. You will stand on a scale that measures weight and body composition through sensor plates you stand on and touch with your hands for 15 seconds. A 'DXA Scan' will require you to lie comfortably on a large table for your body to be scanned to measure your body's amount of fat and muscle and the density of your bones. You will also undergo CT scans to measure the muscle and fat amounts in your abdomen and thighs. These scans are painless but do involve exposure to low doses of x-rays.

N. Heart Rate (pulse) Variability Analysis (15 minutes): We will place small, sticky patches on your chest attached to a chest strap that measures your pulse rate while sitting, standing and walking.

Phase 3: Weight Loss Intervention Program (12 weeks)

During the weight loss phase, you will meet weekly for about an hour with a Registered Dietitian or trained study staff either in person or using an online platform (Zoom) to learn heart healthy diet recommendations for weight loss for 12 weeks. You will be provided with food for at least one meal and 2 snacks per day, recipes for at least two meals per day and dietary counseling to provide 1,300-1,600 calories per day. You may be provided with a daily food item checklist that will be returned to study staff weekly to assess compliance with the provided diet. For those having difficulty with weight loss, we will arrange for you to meet individually with the dietitian or study staff to re-evaluate your diet intake.

You also will participate in supervised exercise training 2 times per week either at one of our two VA GRECC training facilities or on Zoom. The VA GRECC training facilities are located at the BVAMC Annex and the BVAMC Loch Raven Geriatric Wellness Center. Exercise will consist of approximately 30-40 minutes of aerobic exercise (like walking on a treadmill or riding a bike) and 10-20 minutes of strength exercise using resistance bands. You will be asked to perform both aerobic and resistance band exercise on your own at home for a third day of the week. You also will be given a Fitbit (activity monitor). You will be asked to wear the Fitbit daily for the rest of the study to track at home activity. The goal is to achieve between 5,000-10,000 steps/day based upon your walking habits at the beginning of the study. You will be asked about your at home exercise participation at each supervised exercise session.

Phase 5: Weight Maintenance Intervention Programs (24 weeks)

After completion of the 12-week Weight Loss program, you will complete Phase 4 testing (repeat of Phase 2 testing- see below). You will then be randomized (assigned by chance, like flipping a coin) to one of two study groups: 1) weight maintenance or 2) weight maintenance plus intermittent

fasting. You will be instructed to continue your heart healthy routine at home, but without the emphasis on weight loss. Further, you will be instructed to continue the 5,000-10,000 steps per day and three days of resistance band exercises. You may be given a body weight scale to measure your weight at home. You will be called weekly by the study coordinator during the first month of this study phase. After that you will be called every 2 weeks to ask about your dietary intake and body weight. You will also be asked for the activity recorded by the Fitbit for the last three days.

If you are assigned to the **intermittent fasting group**, you will be provided with sample menus and instructed to consume only small meals per day (500 calories per day for women and 600 calories per day for men) one day per week for the entire 24 week participation phase. If you have any difficulties with following the meal plan, our study dietitian will call you to assist with meal plan compliance through collection of a 24-hour diet recall.

Phase 4 and 6: Post Testing after Weight Loss and Weight Maintenance Interventions

All tests that were described in the baseline research testing section (Phase 2) will be performed again following 12 weeks of weight loss (Phase 4- week 12) and 24 weeks of weight maintenance (Phase 6- week 36). These tests will again occur over 4-5 visits and will take approximately 10 hours. As in Phase 2, all tests will occur at BVAMC, except for the muscle sampling test may occur at BVAMC or UMMC-GCRC. We also will ask you to come into the BVAMC sometime during week 48-50 to collect one final vital signs measurement (i.e. resting blood pressure and heart rate), body weight assessment, walking and balance ability assessment, as well as a set of questionnaires about your pain, quality of life, physical activity, and dietary intake.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

We will tell you about any significant new findings which develop during this research which may relate to your willingness to continue participate in this research study.

In general, we will not give you any individual results from the study. If the test results could help you improve your health or prevent future risks to you, the research team will give you and your physician this information.

FUTURE USE OF DATA AND RE-CONTACT

Some participants may want to be re-contacted to consider participating in future studies that might be done utilizing data collected during this study and might require either a specific form of consent or additional participation (either through questionnaires or other data/specimen collection).

_____I agree to be re-contacted to consider participating in future studies

_____I DO NOT agree to be re-contacted to consider participating in future studies

In addition to information relevant for future recruitment, we will also store your data from this study for other research-related purposes.

TISSUE BANKING:

Banked Specimens: While you are in this study blood and muscle samples will be collected from you that may be useful for future research. Some of these samples will be stored in the GRECC at the BVAMC for an indefinite (as long as possible) time period or until none is left. As new testing methods become available, we may measure additional factors that influence cardiovascular health and metabolism (the processes in the body that turns food you eat into energy your body can use). All samples will be coded so that your name cannot be readily identified. The code linking your name to these samples will be kept separately in the BVAMC. Your samples will be used only for research and will not be sold or used for the production of commercial products. Your samples will not be used to generate a cell line for genetic testing.

Reports about research done with your samples will be included in your study file and will be kept confidential. You or your medical care provider will not be provided with the results of these tests as these measurements are for research purposes only and are not of proven medical importance.

For the banked specimens to be used in future research by the BVAMC/ VAMHCS or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimens in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your unused specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimens, you will not be able to withdraw your specimen later because they cannot be linked back to you. To withdraw consent for sample storage, please inform the PI in writing at Baltimore VAMC, BT/GR/18, 10 North Greene Street, Baltimore, MD 21201 to request that your samples be destroyed. Data already collected from your samples may not be destroyed or removed from your study file.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to:

- Follow the instructions given by the PI and study team.
- Report any new medical conditions or new medications you start taking after you begin the study.
- Complete the study procedures (testing and exercise sessions).

- Notify the PI or study team if you get hurt or sick as a result of taking part in this study.
- Notify the PI or study team if you decide to stop participating in the study.

POTENTIAL RISKS/DISCOMFORTS:
There may be risks in this study which are not yet known. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Risks from the research
The investigators have designed this study to learn how well weight maintenance plus intermittent fasting compares to commonly accepted weight maintenance methods. There is a risk that the effectiveness and/or safety of the intermittent fasting group may not be as good as the most commonly accepted weight maintenance methods. You may get a treatment that does not help treat your weight condition or that makes your body weight condition worse.

Risks from the specific research procedures (interventions or procedures)
There are risks to taking part in this research study. Everyone taking part in the study will be watched carefully for any side effects. However, the study staff don't know all the side effects that may happen. Be sure to tell study staff immediately about any side effect that you have while taking part in the study. The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Each test will be discussed again in detail with you by the staff prior to and the day of any procedure. All tests are supervised by trained professional staff. We anticipate no physical, social, or legal risks to you in this study.

A. Blood Sampling: The risks associated with blood sampling include discomfort, bruising, swelling, fainting, and possible infection at the site of sampling. This is minimized by having skilled professionals perform the sampling.

B. Oral Glucose Tolerance Test: There is a small risk of developing low blood sugar (hypoglycemia) after you drink the sugar solution for this test. Signs of low blood sugar include headache, nausea, feeling sweaty, dizzy, weak, and having a fast heartbeat. This is easily corrected by giving you a sugar drink to raise your blood sugar.

C. Caloric Expenditure: The risk associated with the methods of measuring the rate at which your body burns calories is that you may begin to feel claustrophobic when the clear plastic hood is placed over their head. Should this occur, we will remove the hood and stop the test.
D. Walking and Balance: There is a minimal risk of falling during the walking and balance tests. A standby aid is always present. Ample rest periods are provided between tests to limit fatigue during testing.

E. Muscle Strength Testing and Training: The most common risk from strength training is muscle soreness. Other minimal risks that are uncommon with strength testing and training, include musculoskeletal injury and cardiovascular events, such as heart attack, stroke, ruptured intracranial aneurism, aortic dissection, and sudden death in very high-risk populations. These risks will be minimized by:

- Using proper participant intake screening
- Strict adherence to inclusion/exclusion criteria
- Providing direct supervision for all testing and training sessions with qualified personnel
- Providing proper instruction on training techniques before strength training begins.

Muscle soreness and injury can also occur during training. You will be taught proper stretching and exercise techniques to minimize this risk. If soreness does develop, you will stop exercise and be taught how to stretch and ice the sore muscles to relieve the soreness. However, monitoring by trained personnel during exercise training limits the risk for these occurrences.

F. Aerobic Exercise Testing and Training*:* Risks of endurance exercise include:

- Minor discomfort and/or shortness of breath
- Dizziness
- Muscle, joint strains and soreness
- Abnormal blood pressure
- Irregular heartbeats
- Falls

In rare instances the following risks may occur:

- Heart attack
- Stroke
- Asthma
- Muscle injury
- Broken bones

- Death

To minimize risks, the aerobic exercise program will be based on your fitness level. Exercise training will be supervised by qualified personnel. The risk of exercise training is greater at higher exercise intensities (when you are working harder).

G. Muscle Sampling:
When the muscle biopsy is performed, you will receive an injection of 1% lidocaine. The lidocaine will cause temporary numbness of the skin and tissues around the sampling site. This numbness usually resolves in 1-2 hours. Permanent numbness of the skin near the sampling site rarely occurs. Allergic reactions are the most common side effect to lidocaine but are extremely rare and include rash, swelling, or severe allergic reaction. Occasionally, headaches, shivering, nervousness, anxiety, apprehension, cold and in severe cases twitching tremors, slowed breathing and heart problems may occur. During the biopsy you may feel discomfort; this is minimized by the injection of lidocaine. Some people find the biopsy temporarily painful, but this lasts for a very short period of time. There is a slight risk of infection and bleeding into the tissue causing a bruise at the biopsy site. Your biopsy site may be tender for 1-2 days after the procedure. A small scar, less than 1/8 inch usually develops at the site.

H. Physical Activity Monitoring: There are no risks associated with recording physical activity, using the monitor(s), or answering questions about your activity habits.

I. Dietary Intake Monitoring: There are no risks associated with recording your dietary intake.

J. Questionnaires: The interviews and questionnaires you undergo in this study are time consuming and of minimal risk to you.

K. Fecal Analysis: There is no risk associated with collection of a stool sample.

L. Body Composition- Radiation Exposure Risk:
The radiation dose you will receive as a result of taking part in this study includes radiation from the DXA machine and the CT scan. You will receive 408 mrem to your total body, 798 mrem to your bladder, 636 mrem to your ovaries/testes, and 588 mrem to your bone in one year. During participation in this study other organs and tissues may receive lesser radiation doses. The radiation dose you will receive to your total body, bladder, ovaries/testes, and bone is in the range of 300-5000 mrem, which is equivalent to the exposure limit of 5000 mrem per year that is established for

radiation workers such as physicians and X-ray technologists who work with radiation. This level of exposure has never been associated with any definite adverse effects.
Please be aware that this radiation exposure is necessary for research purposes only and is not essential for your medical care.

Please advise your doctor if you have taken part in any other research studies at VAMHCS/UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, e.g. thallium scan of your heart, and scans of your brain.

Body Composition analysis by electrical impedance has no associated risk.

M. Heart Rate Variability: Electrodes may cause temporary reddening of the skin in some individuals.

N. Weight Loss: Possible side effects of weight loss include:

- Headaches
- Irritability
- Fatigue
- Dizziness
- Constipation

They will be minimized by emphasizing gradual weight loss progression. Proper hydration guidelines also will be provided.

O. Intermittent Fasting: Possible side effects of intermittent fasting include:

- Low blood sugar
- Dizziness
- Irritability

If this occurs, the dietitian will work with you to determine a caloric intake that prevents these side effects.

P. Breach of Confidentiality: There will be many steps to insure the protection of your confidential study data/ information. Informed consent will be done in a quiet, private setting. Paper study records will be stored in locked file cabinets in a locked office. Electronic study records will be

stored on computer databases with password protection to protect your confidentiality. All study data will be stored with a unique code to keep your identity confidential. Only the principal investigators and research staff will have access to your name and contact information data that is stored in a secure file. Access to this research data with your identifiable information will be password protected and authorization for password access to this part of the database will be strictly guarded and limited.

POTENTIAL BENEFITS

You may not receive any personal benefits from being in this study. The possible benefits of your participating in this study include improved body composition, general health, and physical function. If new problems are diagnosed (i.e., previously undiagnosed hypertension or diabetes), with your permission, a report will be sent to your health care provider summarizing the results with our recommendation for follow-up evaluation and treatment. You will also learn specifically about your physical fitness and muscle mass. We hope the information learned from this study will benefit other people with similar conditions in the future.

ALTERNATIVES TO PARTICIPATION

Your alternative is to not take part. Other exercise and weight loss/ maintenance programs may be available in your area. Some of these non-VA programs require a fee and others do not.

COSTS TO PARTICIPANTS

It will not cost you anything to participate in this study. However, this research involves several testing and training visits. Parking will be provided but transportation will not be provided. You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

You will be provided with at least 1-2 meals weekly for 12 weeks. You will get to keep the Fitbit and scale after completion of the study. You will also receive a $50.00 compensation after completion of each of the 3 testing phases. You will be paid $25 per month over five months ($125.00 total) during the Weight Maintenance Phase (Phase 5). An additional $100 will be paid for study completion. ($375.00 for completion of the entire study). You will be paid in cash.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve the collection of protected health information (PHI) and personal information about you. As with any scientific research study involving the collection of potentially sensitive medical information, participation in this study may involve a risk of breach of confidentiality. The investigator and research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Your data and samples will be coded to protect your privacy. Your name will be kept separately from the identification codes to ensure maximum protection against confidentiality loss. There may be some instances where your information cannot be coded such as the radiology reports or blood work done in the VA clinical laboratory. All study-related information will be stored in secure locations. Paper reports will be stored in locked cabinets in a locked room. Electronic data will be password protected. In summary, all your data will be stored in secure locations on VA servers and computers.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, regulatory auditors and monitors, the VAMHCS Office of Research Compliance, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP). The monitors, auditors, and the IRB will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access**.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies may destroy records. The VA and VHA must follow these rules. All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.
If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, physical functioning or genetic test results.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Office for Human Research Protections, Institutional Review Board and other offices at University of Maryland-Baltimore that help run and/or oversee studies, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the VA Research Compliance Officer the Government Accountability (GAO), the VA research staff within the VA Hospital, and any appropriate state or federal

government agencies that make rules and policy about how research is done that are not listed above.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

The data and specimens that will be obtained from you during this research project may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we cannot ask for your additional consent.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Withdrawal from this study will not result in any physical, social, economic, legal or psychological adverse consequences. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS. If you are an employee or student, your employment or academic standing at VAMHCS will not be affected by your participation or non-participation in this study. If you withdraw from this study, already collected data may not be removed from the study database. You will be told of any

significant new findings which develop during the study which may affect your willingness to participate in the study.

The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes test explained above in Phase 2. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

CAN I BE REMOVED FROM THE RESEARCH?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- If you have a new medical condition or medication that makes you no longer eligible
- If it would be dangerous for you to continue
- If you do not follow study procedures as directed by the study doctors

The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

VAMHCS Human Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201

The VAMHCS Human Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Participant Name: _____ Date:_____

Title of Study: __Promotion of Successful Weight Management in Overweight and Obese Veterans __

Facility: VA Maryland Health Care System

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date